UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
VICTORIA DIVISION

CALVIN TIMBERLAKE, *et al*,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**CIVIL ACTION NO. V-08-4**
	§	
SYNTHES SPINE, INC., *et al*,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Plaintiff Calvin Timberlake ("Timberlake") brought this action after he underwent surgery implanting the artificial intervertebral disc, ProDisc. Timberlake alleges that the device failed, requiring him to undergo a second surgery and causing him permanent injury. Defendants Synthes Spine Company, L.P. and Spine Solutions, Inc.'s ("Defendants"), which marketed and manufactured Timberlake's ProDisc, now move for summary judgment on the grounds that all of Timberlake's claims are preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act. Having considered the motion, response, reply, record, and applicable law, the Court is of the opinion that Defendants' Motion for Summary Judgment (Dkt. No. 187) should be **GRANTED**.

I. History of the Medical Device Amendments

In response to a multitude of state laws regulating medical devices largely enacted due to the failure of the Dalkon Shield contraceptive in the 1970s, Congress passed the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA) in 1976. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). With the passage of the MDA, Congress established a detailed federal regime for the regulation of medical devices. 21 U.S.C. § 36c *et seq*. The MDA

categorizes medical devices into one of three classes, depending on the risk they pose to the public. *Id.* Class I devices—which include devices such as elastic bandages and examination gloves—are subject to "general controls," the lowest level of federal oversight. 21 U.S.C. § 360c(a)(1)(A). Class II devices are subject to additional oversight called "special controls," and include devices such as powered wheelchairs and surgical drapes. 21 U.S.C. § 360c(a)(1)(B). Class III devices are subject to the highest level of federal oversight, known as "premarket approval" (PMA). 21 U.S.C. § 360c(a)(1)(C). The PMA process is a rigorous process wherein the Food and Drug Administration (FDA) reviews an application and determines whether there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d); *Riegel*, 552 U.S. at 317. Class III devices include devices such as replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators. 21 U.S.C. § 360c(a)(1)(C).

In support of PMA, the applicant must submit, among other things, full reports of all information that is known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for the manufacturing and installation of the device. *See* 21 U.S.C. § 360e(c)(1) (describing the components of a PMA application). After receipt of the required documentation, the FDA reviews the application, spending an average of 1200 hours on each submission before granting marketing approval. *Riegel*, 552 U.S. at 318. Once a device has received premarket approval, the manufacturer cannot change the design, manufacturing process, labeling, or any other characteristic in a manner that would affect the device's "effectiveness or safety" without first applying for, and receiving, supplemental premarket approval. 21 U.S.C. § 360e(d)(6)(A)(I). Class III devices are also subject to ongoing reporting requirements even after receiving approval. 21 U.S.C. § 360i.

II. History of the ProDisc[1]

One such Class III medical device, which is the subject of this litigation, is the Synthes ProDisc-L artificial disc replacement device ("ProDisc"). The ProDisc is used to treat spinal arthroplasty in skeletally mature patients with degenerative disc disease. ProDisc was initially conceptualized and designed between 1987 and 1989 by Dr. Thierry Marnay, in conjunction with a French manufacturer of spinal implants. Dr. Marnay began implanting patients with ProDisc in 1990. In 1996, a German company acquired ProDisc, and in 1999, Defendant Spine Solutions, Inc. ("Spine Solutions") was formed and acquired the rights to ProDisc. ProDisc became commercially available in Europe in 2000.

On July 27, 2001, the FDA granted Spine Solutions conditional approval of its Investigational Device Exemption (IDE) application, allowing Spine Solutions to test the ProDisc on humans in the United States. On November 20, 2001, the FDA granted final approval of Spine Solutions' IDE application, as modified by the FDA. During the IDE process, the FDA reviewed and approved the specific study design for the IDE clinical trial of ProDisc ("ProDisc Clinical Trial"). The ProDisc Clinical Trial began in October 2001 and concluded in 2005.

Defendant Synthes Spine Company, L.P. ("Synthes") purchased Spine Solutions in 2003 and began the ProDisc PMA application process with the FDA on August 24, 2004. During the following months, Synthes was in communication with the FDA regarding revisions and requests for additional information concerning various aspects of the ProDisc PMA application. On April 29, 2005, the FDA notified Synthes that the ProDisc PMA application had been accepted for filing, and from May 2005 to July 2006, Synthes submitted numerous amendments to its application in response to the FDA's comments and requests for information. The ProDisc's full

1. The facts surrounding the history of the ProDisc are based on the affidavit of Francis P. Magee, Chief Technology Officer for Synthes Spine and former Vice President of Research and Development for Spine Solutions (Dkt. No. 187, Ex. 1).

application was approximately 8800 pages long and contained information regarding the ProDisc Clinical Trial, draft package labeling, a draft Summary of Safety and Effectiveness Data, as well as a sample ProDisc device for the FDA's review.

On August 14, 2006, ProDisc received premarket approval by the FDA, subject to certain "Conditions of Approval." The FDA-approved labeling consisted of a number of documents, including a Package Insert, a Technique Guide for surgeons, and a Patient Guide—the contents of which were specified by the FDA both through regulations and through the FDA's review during the PMA process.

III. Timberlake's Allegations Regarding his ProDisc[2]

Timberlake suffered from degenerative disc disease affecting the disc between his 4th and 5th lumbar vertebras (L4-L5 disc) for a number of years. As a result, Timberlake underwent various conservative treatments—including physical therapy, medication, and injections—all without significant relief. On December 14, 2006, two months after the ProDisc received premarket approval from the FDA, Timberlake had a ProDisc surgically implanted in place of his degenerated L4-L5 disc. Five days later, x-rays revealed that the ProDisc had "completely failed." On April 4, 2007, Timberlake underwent a salvage operation to remove the failed ProDisc and fuse his L4 and L5 vertebra together. Due to complications in the surgical removal of the ProDisc, the surgeon was unable to complete the fusion at that time. One week later, Timberlake had a second operation, in which the fusion was completed with the insertion of hardware. The failure of the ProDisc resulted in bilateral fractures at Timberlake's L4 vertebra, causing him disabling pain.

2. The facts and allegations regarding Timberlake and his ProDisc are based on Plaintiffs' Fifth Amended Original Complaint (Dkt. No. 163).

Timberlake maintains that prior to the ProDisc's approval by the FDA and while it was still undergoing Clinical Trials, he began researching alternative treatment options for his degenerative disc disease because traditional treatments were not resolving his condition. Timberlake read multiple reports of the successes of the ProDisc Clinical Trials, discussed the possibility of having the ProDisc implanted with his doctor, and relied on the reports in his ultimate decision to have the ProDisc implanted. However, Timberlake later discovered that the reports he read about the ProDisc were incomplete and misleading. According to Timberlake's Complaint, he would not have had the ProDisc implanted had he been aware of the deceptive manner in which the ProDisc obtained FDA approval during the PMA process.

Timberlake claims that Spine Solutions was originally formed in order to obtain FDA approval for and eventually market the ProDisc. In furtherance of this endeavor, Spine Solutions solicited physicians to conduct the ProDisc Clinical Trials who were also willing to invest in Spine Solutions. According to Timberlake, Spine Solutions believed that having investor-physicians conduct the Clinical Trials would result in their ability to more readily obtain other investors and would ensure that the physicians were "in their pocket" so that the outcome of the Clinical Trials would be favorable. Eventually, Synthes purchased Spine Solutions. Synthes completed the Clinical Trials and ultimately applied for and received premarket approval from the FDA for use of the ProDisc.

However, Timberlake alleges that Synthes and Spine Solutions provided incomplete and misleading information concerning the Clinical Trials to the FDA during the PMA process and failed to disclose to the FDA—and later to Timberlake and the general public—that doctors and clinics that were participating in the Clinical Trials would benefit financially if the FDA approved the ProDisc and from the sale of the device. According to Timberlake, the ProDisc

would not have obtained premarket approval had the FDA been aware of this information, and thus Timberlake would not have ultimately been injured by the device.

In his Fifth Amended Original Complaint, Timberlake alleges causes of action against Defendants for strict liability in tort (products), negligence, breach of express warranty, common law and statutory fraud/misrepresentation, violation of the FDA approval process, and civil conspiracy. Defendants now move for summary judgment on all of Timberlake's claims, on the grounds that they are preempted by the MDA.[3]

IV. Summary Judgment Standard

Summary judgment is proper "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c); *see also Christopher Village, LP v. Retsinas*, 190 F.3d 310, 314 (5th Cir. 1999). "For any matter on which the non-movant would bear the burden of proof at trial . . . , the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Transamerica Ins. Co. v. Avenell*, 66 F.3d 715, 718—19 (5th Cir. 1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 323—25 (1986). To prevent summary judgment, the non-movant must "respond by setting forth specific facts" that indicate a genuine issue of material fact. *Rushing v. Kansas City S. Ry. Co.*, 185 F.3d 496, 505 (5th Cir. 1999).

When considering a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in favor of the

3. Anastasia and Matthew Scott ("Scott Plaintiffs") are also parties to this action. Like Timberlake, Ms. Scott alleges that her ProDisc failed, which required her to undergo a second surgery and caused her permanent injury. Defendants have moved to dismiss and sever the Scott Plaintiffs (Dkt. No. 166), as well as to bifurcate their trials (Dkt. No. 268). As such, the Parties have not yet begun discovery with respect to the Scott Plaintiffs' claims. Thus, Defendants move for summary judgment on Timberlake's claims only at this time.

non-movant. *See Samuel v. Holmes*, 138 F.3d 173, 176 (5th Cir. 1998); *Texas v. Thompson*, 70 F.3d 390, 392 (5th Cir. 1995). "The court may not undertake to evaluate the credibility of the witnesses, weigh the evidence, or resolve factual disputes; so long as the evidence in the record is such that a reasonable jury drawing all inferences in favor of the nonmoving party could arrive at a verdict in that party's favor, the court must deny the motion." *Int'l Shortstop, Inc. v. Rally's, Inc.*, 939 F.2d 1257, 1263 (5th Cir. 1991). However, the non-movant cannot avoid summary judgment by presenting only "conclusory allegations" or "unsubstantiated assertions," such as the bare allegations of a complaint, but must present sufficient evidence, such as sworn testimony in a deposition or affidavit, to create a genuine issue of material fact as to the claim asserted. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc). "Even if the standards of Rule 56 are met, a court has discretion to deny a motion for summary judgment if it believes that 'the better course would be to proceed to a full trial.'" *Freeman v. U.S.*, 2005 WL 3132185, *2 (S.D. Tex. Nov. 22, 2005) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)).

V. MDA Preemption and *Riegel v. Medtronic, Inc.*

As noted by the Supreme Court in *Riegel v. Medtronic, Inc.*, in enacting the MDA, Congress "swept back some state obligations and imposed a regime of detailed federal oversight." 552 U.S. 312, 316 (2008). The MDA contains an express preemption clause that states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel*, the Court set forth a two-prong analysis for determining whether a plaintiff's state law claims are expressly preempted by the MDA. First, a court must determine that the federal government has established requirements that are applicable to the device. *Riegel*, 552 U.S. at 322. If there are federal requirements for the device, the court must next determine whether the plaintiff's state law claim is based on a state requirement with respect to the device that (1) is "different from or in addition to" the federal requirements, and (2) relates to the safety and effectiveness of the device. *Id.* (citing 21 U.S.C. § 360k(a)). If the state requirement is different from or in addition to the federal requirements, then the state requirement is preempted by the MDA. However, the Court also noted an important exception to the express preemption clause for "parallel" claims, stating that the MDA "does not [expressly] prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." *Riegel*, 552 U.S. at 330. Such "parallel" claims are not different from, or in addition to, the federal requirements and thus are not preempted by the MDA. *Id.*

The plaintiff in *Riegel* filed suit after a catheter used in his medical procedure ruptured, alleging that the device was designed, labeled, and manufactured in a manner inconsistent with New York state law. *Id* at 320. The catheter at issue was a Class III device that had undergone the FDA's rigorous PMA process. *Id.* Under the first prong of its preemption analysis, the Court reasoned that the PMA process imposes "requirements" under the MDA. *Id.* at 322. Premarket approval is specific to that individual device, and does not constitute an exemption from federal safety review, but instead the PMA process *is* the federal safety review. *Id.* at 323. Because the PMA process itself establishes federal requirements for a device, the Court concluded that any

Class III medical device that has been approved by that process will satisfy the first prong of the preemption analysis. *Id.*

Under the second prong, the Court considered whether the plaintiff's state law claims were based on state requirements with respect to the device that were "different from or in addition to" the federal requirements. The plaintiff had based his claims on state common-law duties, which the Court equated with "state requirements." *Id* at 324. "Absent other indication, reference to a State's 'requirements' includes its common-law duties," the Court held, and such state "requirements" are preempted when applied to a specific medical device that has undergone premarket approval. *Id.* at 324—25.

VI. Preemption Analysis of Timberlake's State Law Tort Claims

The parties do not dispute that the ProDisc is a Class III medical device subject to federal regulation under the MDA. Thus, the first prong of the *Riegel* test is met. Furthermore, Timberlake's Fifth Amended Original Complaint states claims for strict liability in tort (products), negligence, breach of express warranty, common law and statutory fraud/misrepresentation, violation of the FDA approval process, and civil conspiracy. In each of these claims, Timberlake alleges that the ProDisc was defective and unreasonably dangerous, thus meeting *Riegel*'s second prong requiring that claims relate to the safety and effectiveness of the device. The contested issue is therefore whether Timberlake's claims are different from, or in addition to, the federal requirements, or whether they are "parallel claims."

A. Products Liability—Strict Liability/Negligence

Timberlake complains that Defendants are strictly liable in tort because "the ProDisc as manufactured, designed, labeled, and marketed by Defendants, was defective and unsafe for its

intended use." (Dkt. No. 163 ¶ 94.) Timberlake further alleges that Defendants were negligent in designing, marketing, manufacturing, and labeling his ProDisc device. (*Id.* ¶¶ 89 & 91.)

The Supreme Court in *Riegel* explicitly held that the MDA's preemption provision preempts products liability claims, including claims for negligence and strict liability, brought in the context of PMA-approved medical devices. *Riegel*, 552 U.S. at 325. Even before the *Riegel* decision, the Fifth Circuit held that state-law products liability claims are preempted by the MDA, *Gomez v. St. Jude Medical Daig Div. Inc.*, 442 F.3d 919, 930 (5th Cir. 2006), and "'in the ten months following *Riegel*, courts across the country have applied Section 360(k) broadly, preempting all manner of claims from strict products liability and negligence . . . to failure to warn and manufacturing-and-design defect.'" *Lewkut v. Stryker Corp.*, 2010 WL 1544275, at *7 (S.D. Tex. Apr. 16, 2010) (citing *Lemelle v. Stryker Orthopaedics*, 698 F. Supp. 2d 668 (W.D. La. 2010) (noting that state law product liability claims are preempted by the MDA); *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation* ("*In re Fidelis Leads*"), 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (collecting cases); *Funk v. Stryker*, 673 F.Supp.2d 522, 531 (S.D. Tex. 2009) (dismissing claims for strict liability, negligence, and violations of the DTPA); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *2—*7 (D.N.J. Mar. 5, 2009) (plaintiff's claims for failure to warn, defective manufacture, defective design, negligence and recklessness, breach of warranties, and fraud were preempted); *Horowitz v. Stryker*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (plaintiff's negligence, defective manufacturing, defective design, breach of warranty, and failure to warn claims were preempted by the MDA and FDCA)).

Timberlake complains that such an "overly broad interpretation of the MDA and the *Riegel* case . . . would virtually wipe out every state law claim that has anything to do with a medical device." (Dkt. No 217 at 3.) Justice Ginsburg expressed the same concern in her

dissenting opinion in *Riegel*, stating that it was "difficult to believe that Congress would, without comment, remove all means of judicial recourse for consumers injured by FDA-approved devices." *Riegel*, 552 U.S. at 336 (Ginsburg, J., dissenting) (internal quotation omitted). Justice Scalia, writing for the majority, responded that the removal of all judicial recourse "is exactly what a pre-emption clause for medical devices does by its terms." *Id.* at 326. While "[i]t is not our job to speculate upon congressional motives," Justice Scalia noted, "the text of the statute suggests that the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Id.*

"In accordance with the high degree of consensus apparent in this case law, this Court must, therefore, recognize that [Timberlake's] state law claims of negligence [and] strict products liability . . . do impose additional safety requirements such that they would be preempted under *Riegel* by the federal requirements inherent in the PMA process." *See Lewkut*, 2010 WL 1544275 at *7. Defendants are therefore entitled to summary judgment as a matter of law on these claims.

Still, "*Riegel* left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted." *In re Fidelis Leads*, 592 F. Supp. 2d at 1152 (citing *Riegel*, 552 U.S. at 330; *Stevens v. Pacesetter, Inc.*, 2008 WL 2637417, at *1 (D.S.C. Apr. 1, 2008) (noting that a "narrow category" of claims survive *Riegel*—those "alleging a failure to comply with the federal standards which were established through the PMA process")). Thus, Timberlake's claim that "the ProDisc[] that [was] implanted in Calvin Timberlake [was] not manufactured and labeled as represented to and

approved by the FDA" (Dkt. No. 163 ¶ 94; *see also Id* ¶ 89) is not expressly preempted, and will be considered in Part VII.B *infra*.

B. Breach of Express Warranty

Timberlake alleges that "Defendants made express warranties to the public generally, and specifically to Plaintiff[]. The Defendants breached the warranties." (Dkt. No. 163 ¶ 99.) While Timberlake's Fifth Amended Complaint does not refer to any specific warranty made to him or breached by Defendants, in response to Defendants' motion for summary judgment, Timberlake contends that Defendants "made warranties to him concerning the level of success of the ProDisc trials and the types of testing that were done; that these studies were carried out by independent and disinterested physicians; that they failed to disclose the bad results from the testing[;] and that there was no reasonable salvage surgery available." (Dkt. No. 217 at 4; *see also Id.* at 11.) Timberlake contends that he relied on these warranties—which he read in "Defendants' promotion material" and on the Internet on "drugs blogs and things like that"—before deciding to have the ProDisc implanted. (*Id.* at 6, ¶ 9; *Id.*, Ex. B at 322—23.) In sum, based on statements that Timberlake read about the ProDisc, he believed that the ProDisc was safe, but the device ultimately failed and caused him permanent injury and pain. Timberlake's breach of express warranty claim is therefore based on the allegation that Defendants represented to him that the ProDisc was safe and effective, but that the ProDisc was in fact not safe and was ineffective.

Prior to the *Riegel* decision,[4] the Fifth Circuit held that the MDA preempts express warranty claims when:

> A jury hearing [a plaintiff's] state-law breach of express warranty claim would have to decide whether [the manufacturer's] representations about the [device] were true. Because those representations—including the label [and]

4. As noted in *In re Fidelis Leads*, "The Supreme Court did not opine on express-warranty claims in *Riegel*, because the plaintiffs did not challenge the dismissal of those claims on appeal." 592 F. Supp. 2d at 1164 n.21.

> warnings . . .—were approved by the FDA through the PMA process, the duties arising under the [state] breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme.

Gomez, 442 F.3d at 932. Even assuming that that the statements Timberlake read on the Internet were made by Defendants and constituted express warranties under Texas law, a jury would still have to decide that the ProDisc was unsafe and ineffective in order to find that Defendants breached these warranties. Because the FDA determined that the ProDisc was safe and effective when granting Defendants' PMA application, Timberlake's claim for breach of express warranty is preempted. Defendants are therefore entitled to summary judgment as a matter of law on this claim.

C. Fraud/Misrepresentation

Timberlake next contends that Defendants committed "fraud as to the FDA, the public and the Plaintiffs" by making "false representations . . . regarding the performance capabilities of the ProDisc." (Dkt. No. 163 ¶ 60.) Timberlake further alleges that Defendants "failed to disclose . . . problems with ProDisc's design and performance," "ma[de] express representations . . . concerning ProDisc safety and effectiveness, which exceeded the performance capabilities presented by the defendants to the FDA," and "misrepresent[ed] the nature, history, and result of the Clinical Trials." (*Id.*) In addition, Timberlake claims that Defendants failed to disclose "that doctors and clinics . . . participating in the Clinical Trials would benefit financially if the FDA approved the device." (*Id.*) In sum, Timberlake's fraud and misrepresentation claims are premised on attacks on the ProDisc device's design; the ProDisc Clinical Trial's study design, outcome, and data; the ProDisc product warning label; and the financial disclosure information reviewed by the FDA prior to the ProDisc Clinical Trials and throughout the PMA process.

To the extent Timberlake complains about the information provided to patients and physicians regarding the ProDisc, his fraud claim is, "'at bottom, a failure to warn claim.'" *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37, 45 (D. Mass. 1994) (quoting *King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir. 1993)). Timberlake cannot escape that under his theory of liability, Defendants would have been required to provide information to patients and physicians above and beyond those on the ProDisc's Package Insert, Technique Guide for surgeons, and Patient Guide—all of which were specifically approved by the FDA as part of the ProDisc Conditions of Approval. *See* 21 U.S.C. § 360c(a)(2)(B); *In re Fidelis Leads*, 592 F. Supp. 2d at 1159. Mandating that Defendants provide information and warnings to patients and physicians would impose requirements "different from, or in addition to" those approved by the FDA. Moreover, as recognized by the *Riegel* Court, the PMA process necessarily involves a determination that the FDA-approved label for the subject medical device is neither "false nor misleading," and that state common law requirements for additional warnings are preempted. *Riegel*, 552 U.S. at 318, 329.

Accordingly, the Court finds that Timberlake's claims for fraud and misrepresentation as to the public and himself are preempted, and Defendants are therefore entitled to summary judgment as a matter of law on these claims. The Court will address Timberlake's claims that Defendants defrauded the FDA below.

VII. Analysis of Timberlake's Purported "Parallel Claims"

Timberlake contends that his claims arising from Defendants' alleged fraudulent conduct during the PMA process are "parallel claims" arising from Defendants' violations of FDCA requirements, and are therefore not preempted by *Riegel*. Timberlake further argues that his remaining state law tort claims escape *Riegel* preemption because Defendants fraudulently

obtained FDA approval for the ProDisc, and he only seeks to enforce "the very safety and effectiveness requirements that the FDA does impose." (Dkt. No. 217 at 4.)

A. Fraud as to the FDA/Violation of the FDA Approval Process

As noted in Part VI.C *supra*, Timberlake alleges that Defendants committed "fraud as to the FDA" by making false representations regarding the performance capabilities of the ProDisc and the nature, history, and result of the Clinical Trials. (Dkt. No. 163 ¶ 60.) Specifically, Timberlake alleges that Defendants failed to disclose to the FDA problems with ProDisc's design and performance, that doctors and clinics participating in the Clinical Trials would benefit financially if the FDA approved the device, and that no reasonable salvage surgery existed in the event the device failed. Timberlake further alleges that Defendants misrepresented their claims of a faster recovery than conventional measures for disc replacement and attempted to persuade the FDA that the ProDisc was substantially similar to another artificial disc, the Charite, when it was not.

Timberlake also brings claims against Defendants for "violation of the FDA approval process" (Dkt. No. 163 ¶ 4), on the basis that "Defendants negligently failed to comply with the process set forth by the FDA for approval of medical devices such as the ProDisc" and were therefore able to "circumvent[] the Pre-Marketing Approval process set out by the FDA." (*Id.* ¶¶ 90 & 95.) "Because of the misrepresentations in the PMA process," Timberlake alleges, "the ProDisc was defective and because it was defective, it dislodged in Mr. Timberlake, causing serious and debilitating injuries, pain, and other damages." (Dkt. No. 217 at 11.)

In a 2001 Supreme Court case nearly identical to this action,[5] patients claimed to have suffered injuries following the implantation of orthopedic bone screws into pedicles of their spines. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The patients sued the consulting company that assisted the screws' manufacturer in navigating the federal regulatory process for these Class III devices, alleging that the company made fraudulent representations to the FDA in the course of obtaining approval to market the screws. Plaintiffs sought damages under state tort law, claiming that had the misrepresentations not been made, the FDA would not have approved the screws, and the plaintiffs would not have been injured. After finding "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government," in 21 U.S.C. § 337(a),[6] the Supreme Court held that the plaintiffs' state law claims for fraud on the FDA were impliedly preempted by the FDCA, as amended by the MDA. *Id.* at 352—53. Although "citizens may report wrongdoing and petition the agency to take action," there is no private right of action under the FDCA. *Id.* at 349 (citing 21 C.F.R. § 10.30).

Timberlake contends that his claims arising from Defendants' alleged fraudulent conduct during the FDA approval process are not merely fraud on the FDA claims, but are "parallel claims" arising from violations of FDCA requirements. The Court rejected an identical argument made by the plaintiffs in *Buckman* on the grounds that their "fraud claims exist[ed] solely by virtue of the FDCA disclosure requirements." *Buckman*, 531 U.S. at 353. Numerous federal

5. The Court uses the term "nearly" because the manufacturer of the bone screws in *Buckman* sought approval under an exception to the PMA requirement that existed for devices that were already on the market prior to the MDA's enactment in 1976. *See* 21 U.S.C. § 360e(b)(1)(A). "The MDA allows these 'predicate' devices to remain available until the FDA initiates and completes the PMA process" and "allows other manufacturers to distribute (also pending completion of the predicate device's PMA review) devices that are shown to be 'substantially equivalent' to a predicate device." *Buckman*, 531 U.S. at 345 (citing § 360e(b)(1)(B)). Demonstrating that a device qualifies for this exemption is known as the "§ 510(k) process," which refers to the original sections of the MDA containing this provision. *Id.* This distinction does not affect the Court's analysis of Timberlake's claims.

6. Pursuant to 21 United States Code Section 337, "Except as provided in subsection (b) of this section [allowing States to enforce certain provisions related to food], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."

courts construing *Buckman* and *Riegel* have also recognized that so-called "parallel claims" alleging violations of the FDA approval process are equivalent to fraud on the FDA claims, and thus *Buckman* preemption applies. *See, e.g.*, *Hughes v. Boston Scientific Corp.*, 669 F. Supp. 2d 701, 711 (S.D. Miss. 2009); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 786 (D. Minn. 2009); *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008); *Clark v. Medtronic, Inc*,. 572 F. Supp. 2d 1090 (D. Minn. 2008). As recognized by another district court in a similar case:

> It might seem inconsistent with *Riegel* to conclude that a claim alleging a medical-device manufacturer violated the FDCA is preempted. After all, *Riegel* expressly recognized that "parallel" claims—that is, claims "premised on a violation of FDA regulations"—are not preempted. Plaintiffs noted this inconsistency at oral argument, asserting that if they cannot bring state-law claims for violations of the FDCA, then there exist no "parallel" claims that could possibly survive preemption—in essence, "different from, or in addition to" in Section 360k(a) would be rendered meaningless. If Congress had intended that result, Plaintiffs argued, it could have easily said so.
>
> But what this argument overlooks is that claims alleging violations of the FDCA are not preempted because they run afoul of Section 360k(a), which is the type of preemption addressed in *Riegel*. Rather, such claims are impliedly preempted by 21 U.S.C. § 337(a), which states that all proceedings for the enforcement or to restrain violations of the FDCA "shall be by and in the name of the United States." Hence, "the FDCA leaves no doubt that it is the Federal Government rather than private litigants [which is] authorized to file suit for noncompliance with the medical device provisions" in the FDCA. As a result, when Sections 337(a) and 360k(a)—as construed in *Buckman* and *Riegel*, respectively—are read together, nearly all types of claims concerning FDA-approved medical devices are preempted.

In re Fidelis Leads, 592 F. Supp. 2d at 1161 (internal citations omitted).

Accordingly, the Court finds that Timberlake's claims for "fraud as to the FDA" and "violation of the FDA approval process" are preempted. Defendants are therefore entitled to summary judgment as a matter of law on these claims.

B. Products Liability—Strict Liability/Negligence

As evident by the numerous decisions cited herein, nearly all types of claims concerning FDA-approved Class III medical devices are preempted. However, the *Riegel* Court left open a narrow window for truly "parallel" state law claims, such as claims that the device or its label deviated from the PMA approved by the FDA.

Timberlake brings claims against Defendants under theories of strict products liability and negligence on the basis that "the ProDisc[] that [was] implanted in Calvin Timberlake [was] not manufactured and labeled as represented to and approved by the FDA . . . and as such violated federal law." (Dkt. No. 163 ¶¶ 89 & 94.) Although these claims may be considered "parallel claims" under *Riegel*, as Defendants point out, "[Timberlake] cannot simply incant the magic words '[Defendants] violated FDA regulations' in order to avoid preemption." *In re Medtronic Leads*, 592 F. Supp. 2d at 1158. Instead, Timberlake must plead and prove the specific way in which Defendants' manufacturing process differed from that approved by the FDA in order to show that his manufacturing defect claim is truly "parallel." *See id.*; *Lemelle*, 698 F. Supp. 2d at 678. Likewise, in order for Timberlake's labeling defect claim to escape preemption, he must offer evidence that the label on his ProDisc differed from the label approved by the FDA. *See id.*

In response to Defendants' motion for summary judgment, Timberlake elaborated that "[d]uring the PMA process, the Defendants violated the FDA's monitoring requirements, and their manufacturing and packaging facilities failed inspection. These misrepresentations and negligence resulted in an unreasonably defective design." (Dkt No. 217 at 5.) Timberlake also

offered the affidavits, deposition testimony, and reports of several expert witnesses,[7] who identified five key defects in the ProDisc System:

> 1. The ProDisc-L implant inlay-endplate component lock mechanism is defective . . . ;
>
> 2. Aspects of the *testing and analyses* were incomplete or deficient . . . ;
>
> 3. Aspects of the *surgeon training* were incomplete or deficient relative to (1) the ability of the surgeon to detect the appropriate and safe installation, and (2) the biomechanical effect of malpositioning . . . ;
>
> 4. Because the ProDisc-L implant's insertion tools do no[t] assure that [the] polyethylene implant is snapped in place when used, they are defective . . . ;
>
> 5. The relative motion of the Synthes ProDisc-L insertion tool and the implant during inlay insertion is a *design defect* because it can cause implant damage and can prevent the inlay from being properly locked in position during installation.

(*Id.* at 12 (emphasis added).)

To the extent Timberlake alleges the ProDisc's testing, labeling, and design were defective (in Numbers 2, 3, and 5, respectively), as noted *supra*, such claims involving Class III devices that have obtained premarket approval are preempted under *Riegel*. With respect to Numbers 1 and 4, it is unclear whether Plaintiff is alleging that the inlay-endplate component lock mechanism and insertion tools for *all* ProDiscs are defective, which would be a design defect claim, or whether he is claiming that those aspects of only *his* Pro-Disc are defective, which would be a manufacturing defect claim. Although Timberlake has offered expert opinion supporting his claim that the ProDisc's locking mechanism and insertion tools are defectively designed, he has failed to cite to any evidence in the record, including his own experts'

7. Defendants have filed numerous objections, including *Daubert* challenges, to Timberlake's expert witnesses (Dkt Nos. 172, 178, 180, 233, 234, & 236). Even assuming that Plaintiff's proffered experts are qualified to give opinion testimony in this case, their opinions relate to Plaintiff's claims for design defect, "fraud as to the FDA," and "violation of the FDA approval process"—claims that the Court has determined are preempted. Accordingly, Defendants' motions regarding Timberlake's experts (Dkt Nos. 172, 178, 180, 233, 234, & 236) are **DENIED** as moot.

testimony, showing that Defendants violated the specifications imposed by the FDA as part of the ProDisc's PMA with respect to the manufacturing and labeling of *his* ProDisc.[8] To the contrary, the evidence set forth by Defendants shows that the ProDisc implanted into Timberlake was properly manufactured in accordance with all design, manufacturing, and labeling specifications imposed by the FDA as part of the ProDisc's PMA, at the time the ProDisc left Defendants' control. (Nichols Aff., Dkt. No. 187, Ex. 2 ¶¶ 5—8.)

The Court finds that Timberlake has failed to offer proof sufficient to create an issue of fact on his "parallel claims" that Defendants did not manufacture or label his ProDisc in a manner consistent with that approved by the FDA in the ProDisc's PMA. Defendants are therefore entitled to summary judgment on these claims.

VIII. Civil Conspiracy

Finally, Timberlake alleges "Defendants acted together to perpetuate an unlawful conspiracy to the damage of the Plaintiff[]. Defendants had knowledge of, agreed to, and intended a common objective or course of action that resulted in damage to the Plaintiff[]. . . . From the inception, the Defendants were aware of the harm to patients such as Calvin Timberlake . . . that would likely result from their conduct." (Dkt. No. 163 ¶¶ 101 & 102.)

In order to establish a claim for civil conspiracy under Texas law, a plaintiff must establish the following elements: "'(1) two or more persons; (2) an object to be accomplished;

8. Upon a complete review of the record, the Court notes that Timberlake's FDA expert, James Walters, J.D., M.S., stated that Synthes' Monument, Colorado manufacturing facility failed an FDA inspection in March 2006, and "Synthes [could not] demonstrate that the devices were manufactured in accordance to specification." (Walters Aff., Dkt. No. 217, Ex. A, Supp. No. 2 at 23.) To the extent any such violations occurred during the PMA approval process, the Court has already found that Timberlake's claims for "violation of the FDA approval process" are preempted under *Buckman*. Walters offered no testimony that Timberlake's ProDisc was manufactured at the Monument, Colorado facility, or that Synthes deviated from the ProDisc's PMA specifications after receiving premarket approval on August 14, 2006. To the contrary, Timberlake's biomedical engineering experts, Dr. Jamie R. Williams, PhD. and Mari S. Truman, P.E., stated that Timberlake's "implant was machined per print at the Synthes production facility." (Williams & Truman Aff., Dkt. No. 217, Ex. C at 8.) Moreover, although Williams and Truman complain that Timberlake's ProDisc may have failed because Synthes failed to perform additional testing and measurements post-manufacturing or post-shipping, Timberlake has provided no evidence that the FDA required this additional testing as part of the ProDisc's PMA.

(3) a meeting of minds on the object or course of action; (4) one or more unlawful, overt acts; and (5) damages as the proximate result.'" *Apani Southwest, Inc. v. Coca-Cola Enterprises, Inc.*, 300 F.3d 620, 635 (5th Cir. 2002) (quoting *Massey v. Armco Steel Co.*, 652 S.W.2d 932, 934 (Tex. 1983)). Because civil conspiracy is a "derivative tort" under Texas law, "[i]f a plaintiff fails to state a separate underlying claim on which the court may grant relief, then a claim for civil conspiracy necessarily fails." *Meadows v. Hartford Life Ins. Co.*, 492 F.3d 634, 640 (5th Cir. 2007) (citing *Tilton v. Marshall*, 925 S.W.2d 672, 681 (Tex. 1996)).

Because the Court has determined that all of Timberlake's other claims are preempted or otherwise factually deficient, his claim for civil conspiracy must fail for lack of an underlying claim to support it. Defendants are therefore entitled to summary judgment on this claim.

IX. Conclusion

For the reasons set forth above, Defendants' Motion for Summary Judgment (Dkt. No. 187) is **GRANTED**, and Plaintiff Calvin Timberlake's claims are hereby **DISMISSED**.

It is so **ORDERED**.

SIGNED this 18th day of February, 2011.

JOHN D. RAINEY
SENIOR U.S. DISTRICT JUDGE